UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,143	05/06/2004	Jayant Ekanth Khanolkar	9626	7415

27752 7590 10/03/2011

THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/03/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/840,143
Filing Date: May 06, 2004
Appellant(s): KHANOLKAR ET AL.

Mr. Jerry J. Yetter
For Appellants

EXAMINER'S ANSWER

This is in response to the Appeal Brief filed 14 July 2011, appealing from the Office action mailed 22 December 2010.

(1) Real Party in Interest

The Examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-4, 6-12 and 14-17 are pending and are presently finally rejected.

(4) Status of Amendments After Final

The Examiner has no comment on the Appellants' statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The Examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The Examiner has no comment on the copy of the appealed claims contained in the Appendix to the Appellants' brief.

(8) Evidence Relied Upon

- US PGPub 2003/013377 Dobrozsi et al. 06-2003
- WO 94/25008 White, Richard Keim 11-1994
- Kennedy (1996): "The Thinking Person's Guide to Perfect Health: Chelation"

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Appellants are advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Dobrozsi et al. (US Pre-Grant Publication N° 2003/013377) and White (WO 94/25008) in further view of Kennedy (*The Thinking Person's Guide to Perfect Health: Chelation*).

The amended recitations of the base claims 1 and 11 are respectively directed to a soft gelatin-encapsulated pharmaceutical composition and a method of providing said composition. The Examiner broadly and reasonably interprets claim 11 as reciting the same subject matter as claim 1, particularly since the instantly claimed method recites the steps of "providing" the formulation of claim 1 and encapsulating said formulation in a soft gelatin capsule.

The instantly claimed encapsulated composition is recited as comprising: a.) about 55% to about 90% by weight of the composition of an active pharmaceutical ingredient, b.) about 0.001% to about 1.0% by weight of the composition of a stabilizing agent such as disodium EDTA, and c.) about 9% to about 39% by weight of the composition of a solvent.

The teachings of Dobrozsi are drawn to a the preparation of stable liquid pharmaceutical compositions containing concentrated levels of pharmaceutical active ingredients, in addition to hydrophilic solvents, water and compounds such as stabilizers ¶[0021]. Such end-use compositions or exact dosing measuring "devices" which are taught include liquid filled edible capsules. Soft gelatin capsules are specifically taught in Example 13. Each of the Examples

teaches incorporating the stabilizer disodium EDTA in an amount ranging from 0.02-0.91 wt%, thereby also teaching the limitations of claims 4, 6 and 14. The hydrophilic solvents which are used include both polyethylene glycol and propylene glycol, wherein said solvents are present in amounts as low as about 30 percent by weight of the composition ¶¶[0044] and [0045]. Paragraph [0048] teaches the optional inclusion of additional ingredients such as antioxidants. The concentrated active ingredients are taught as comprising as much as about 40% by weight of the composition ¶[0034]. This is where Dobrozsi falls short of teaching the instantly claimed invention.

However, the teachings of White remedy this deficiency particularly since the invention is directed to a method for preparing pharmaceutical compositions, which preferably comprise from about 0.01% to about 50% by weight of a pharmaceutically active ingredient (claim 1; pg 8, lines 14-16). Claims 1 and 5 further expressly teach incorporating such hydrophilic solvent compositions as polyvinyl pyrrolidone (i.e. preferably 10-50% by weight PVP) and polyethylene glycol in amounts as high as 20% by weight. Claim 9 and Example VIII are expressly drawn to teachings whereby the active composition formed is encapsulated within a soft gelatin capsule. Further regarding Example VIII, the method expressly teaches heating and mixing PVP and polyethylene glycol (e.g. 20% w/w of the composition) prior to the adding the active ingredient (e.g. acetaminophen) to the solvent blend in the amount of 57.14% w/w of the composition. This creates a "supersaturated solution" wherein the majority of the drug remains in suspended form. The teachings of Example VIII are also considered by the Examiner as reading on the limitations recited by claim 2 wherein the active ingredient suspended within the capsule comprises "about 58% by weight of the composition". This limitation is interpreted in light of Appellants'

specification (see MPEP §2111), particularly Sample 5 (pg. 10; Table), wherein the composition which is commensurate in scope with the limitations of claim 2 (e.g. about 58 wt%) dedicates 58.6 wt% to the pharmaceutically active compound. Though there is no lower limit expressly defined by Appellants for "about 58%", the Examiner broadly and reasonably interprets said limitation as encompassing amounts which are at within ± 1 wt% of this amount.

The invention of White is deficient such that no express teaching of a "stabilizing agent" is provided. However, similar to the teachings of Dobrozsi, White teaches that antioxidant compounds may be added to the formulation as optional ingredients (pg. 12, lines 31-33).

The limitations of claims 3 and 12 recite different categories of pharmaceutically active ingredients which may be suspended within the capsule formulation. The invention of Dobrozsi expressly teaches the use of compounds such as antihistamines, antitussives, expectorants/mucolytics, bronchodilators and decongestants ¶¶[0028]-[0033]. The invention of White expressly teaches using similar types of pharmaceutically active ingredients such as antitussives, antihistamines, decongestants, expectorants and analgesics (Claim 7).

The limitations of claims 7 and 10 recite that the overall composition further comprises about 0.1 wt% to about 5.0 wt% water. The invention to Dobrozsi expressly teaches this limitation wherein the formulations may also include water in amounts as low as about 5% by weight of the composition ¶[0046]. The formulations of White again expressly teach that the formulations may comprise water mixed with or in addition to polyethylene glycol and may also range from 0.1% to 20% by weight (claim 5).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated a stabilizing agent such as disodium EDTA into a supersaturated active suspension such as the one which is taught by White. The ordinarily skilled artisan would have been highly motivated to do so particularly since Dobrozsi is expressly directed to the preparation of formulations wherein the active ingredients are more difficult to solubilize. Furthermore, higher concentrations of such actives not only increase the likely instability of the overall formulation, but also the likelihood for the precipitation and presence of contaminants as well ¶[0025]. As such, the invention of Dobrozsi seeks to stabilize more concentrated formulations using compounds such as disodium EDTA. White, when considered in light of the teachings of Kennedy, is considered by the Examiner as teaching EDTA compounds as an optional ingredient which may be added to the suspension formulations. In particular, Kennedy generally teaches that EDTA may act as a powerful antioxidant in the presence of radical compounds (pg. 5, points 3 and 7). Thus, when considered in further view with the teachings of Dobrozsi, which *do* add disodium EDTA for the sake of stability of the formulation, it follows that the skilled artisan would again be highly motivated to add a powerful antioxidant such as EDTA to the formulation(s) of White, and expect to arrive at the instantly claimed invention.

Thus, based on the teachings of the combined references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

(10) Response to Argument

Appellants' arguments with regard to the rejection of claims 1-4, 6-12 and 15-17 under 35 USC 103(a) as being unpatentable over the combined teachings of Dobrozsi et al. (US Pre-Grant Publication N° 2003/013377) and White (WO 94/25008) in further view of Kennedy (*The Thinking Person's Guide to Perfect Health: Chelation*) have been fully considered but they are not persuasive.

Appellants acknowledge on the record that the Dobrozsi reference was published on 19 June 2003, whereas the earliest effective filing date accorded to the instant application is 6 May 2004. Appellants continue to traverse the rejection and clearly state that "[t]he controlling issue in this Appeal is whether the Examiner is correct and the Dobrozsi document is applicable with White and/or Kennedy as §103 art against the present invention *via* §102(a), or whether Appellants are correct and Dobrozsi is applicable under §103 only *via* 102(e) and, thus, is subject to 103(c)."

It remains Appellants' position that the Dobrozsi reference "only qualifies as prior art under 35 USC §102(e)" and that because the present application and Dobrozsi reference were commonly assigned to Proctor & Gamble Company at the time of the instant invention, that the Dobrozsi reference is unavailable as art under 35 USC §103(c) citing Example 4 of MPEP §706.02(k) in support. Appellants also refer to MPEP §706.02(a)(B) in an attempt to describe the '377 reference as a "new category of prior art".

In response, the Examiner partially agrees with Appellants' position. It is agreed that if the Dobrozsi reference employed in the obviousness rejection under 35 USC §103(a) were

available as prior art under section 102(e) ***only*** (i.e., available for use by only its filing date), then Appellants would have met their burden in overcoming the instant rejection [emphasis added]. However, the Examiner respectfully maintains that this is not the case.

The Examiner respectfully maintains that the Dobrozsi reference is in fact available as prior art under 35 USC 102(a). The publication date of the reference, which is 19 June 2003, falls ***prior to, but less than one year before the earliest effective filing date*** of the instant application which is 6 May 2004 [emphasis added]. Further, ***the inventive entity of the reference is also different from that of the instant application*** [emphasis added]. Appellants are respectfully directed to MPEP §2132.01 concerning publications as 35 USC 102(a) prior art, in which is provided a discussion for rebutting a *prima facie* case of obviousness using such a reference. Appellants are further directed to MPEP §2141.01(I), the title of which states that "[p]rior art available under 35 USC 102 is available under 35 USC 103" wherein "[a] 35 USC 103 rejection is based on 35 USC 102(a), 102(b), 102(e), etc. depending on the type of prior art reference used and its publication or issue date."

Thus, as previously argued, and also in accordance with MPEP §2146, only references which qualify as prior art under 35 USC §102(e), (f), and/or (g), may be excluded under 35 USC §103(c). Since Dobrozsi remains available as prior art under 35 USC §102(a), it ***cannot*** be excluded in this manner [emphasis added].

For these reasons, Appellants' arguments remain unpersuasive. Said rejection is therefore **maintained**.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the Examiner in the Related Appeals and Interferences section of this Examiner's Answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jeffrey T. Palenik/

Examiner, Art Unit 1615

Conferees:

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612